

REMARKS

Applicant acknowledges the entry of the RCE dated 9/21/07 and the withdrawal of all previous rejections in view of the submission of all new claims upon entry of the RCE. Claims 29-42 are pending in this application. Claims 29-42 are rejected. Claim 34 is amended for purposes of clarification.

Double patenting rejection

Claims 29-42 have been rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1-20 of U.S. Patent No. 6,881,546. The Examiner asserts that while the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to treating an acute myocardial ischemic event whereas the claims of '546 are directed to treating cardiovascular disease in general by the same method.

U.S. Patent No. 6,881, 546 claims "A method for treating or preventing cardiovascular or cerebrovascular disease in a patient, comprising administering to said patient an effective amount of an **agent that binds a sphingolipid or a sphingolipid metabolite** to reduce effectively the concentration of sphingolipid or sphingolipid metabolite thereby treating or preventing cardiovascular or cerebrovascular disease in said patient." (Emphasis added).

In contrast, the current application claims "A method of treatment, comprising administering to a mammal known or suspected to be suffering or to have suffered an acute myocardial ischemic event a therapeutically effective amount of an **agent that alters the activity or concentration of an enzyme** in an amount effective to treat acute myocardial ischemia, **wherein said enzyme catalyzes a reaction that produces or degrades a sphingolipid or a sphingolipid metabolite**, and wherein said agent is selected from the group consisting of a small molecule, a protein, a polypeptide, and a polypeptide derivative, thereby effecting treatment. (Emphasis added).

Thus it can not be said that these two methods are the same, as the Office Action erroneously states, because the two methods use two entirely different agents, and achieve different therapeutic effects. Applicant's invention is directed to treating acute myocardial ischemia, i.e., a restriction in or deficiency of oxygenated blood flow in the

myocardium (heart muscle tissue), once it has occurred, in order to limit further damage caused by the acute ischemic event. This is distinct from prevention or treatment of cardiovascular or cerebrovascular conditions. In addition, Applicant's current invention is directed to use of an agent that alters the activity or concentration of an **enzyme that catalyzes a reaction that produces or degrades a sphingolipid or a sphingolipid metabolite**, while the '546 claims are directed to use of an agent that binds a **sphingolipid or a sphingolipid metabolite**. Thus, one method employs an agent that alters the activity or concentration of an enzyme (i.e., a protein) and one method employs an agent that binds a sphingolipid or metabolite thereof (i.e., a lipid), and thus the two methods cannot be said to be the same. Applicants argue that because the two methods are distinct, a terminal disclaimer is neither necessary nor appropriate.

Rejection under 35 U.S.C. §103(a)

Claims 29-42 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over the combination of Gamble and Tabas in view of Applicant's admissions in the specification, in further view of Friedrichs.

Applicant's invention is directed to treating acute myocardial ischemia, i.e., a restriction in or deficiency of oxygenated blood flow in the myocardium (heart muscle tissue), once it has occurred, in order to limit further damage caused by the acute ischemic event, e.g., sudden cardiac death, myocardial tissue damage, myocardial cell death, reperfusion damage, myocardial infarction or heart failure resulting from ischemic damage. This is distinct from prevention or treatment of vascular conditions such as coronary heart disease, also known as coronary artery disease, which is an obstruction of the arteries that supply the heart due to gradual accumulation of atherosclerotic plaques over time. While Gamble ('362) uses the redundant term "coronary heart disease," this term is synonymous with the more explanatory term, "coronary artery disease" and in fact Gamble's initially uses the even more explicit term "atherosclerotic coronary heart disease" when introducing the disease state in the background of the invention.

As characterized by the Examiner, Tabas ('322) also teaches methods for treating conditions including atherosclerotic vascular disease, coronary artery disease and cerebral vascular diseases. Thus both Tabas and Gamble teach methods of treating vascular disease, as opposed to methods of treating acute myocardial ischemia which is

Applicant's invention. The Examiner has cited Friedrichs (US20020150582) as curing this deficiency. Regardless of what Friedrichs teaches, this reference is not available as a prior art reference because it was published on 10/17/2002, ten months after Applicant's filing date. 35 U.S.C. §103(a), the basis for the obviousness rejection, states that the differences between the subject matter sought to be patented and the prior art must be "such that the subject matter as a whole would have been obvious **at the time the invention was made**". The Friedrichs reference, therefore, could not have rendered anything obvious even as of Applicant's filing date (much less as of the date of Applicant's invention), as Friedrichs did not publish until late in the following year. Applicant respectfully requests that this rejection be withdrawn.

Rejection under 35 U.S.C. §112:

Claim 34 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite because the Examiner feels it is unclear if both or either (a) and (b) are included in the agent. Claim 34 has been amended to insert the word "or" at the end of section (a), to indicate that the agent may be (a) or (b) or (c). Thus the claims are believed to be in condition for allowance.

Conclusion

Applicant respectfully submits that the pending claims are in condition for allowance, and earnestly solicits prompt issuance of a notice to such effect. If any issue remains outstanding that can be addressed without the need for an additional formal action and response thereto, the Examiner is encouraged to telephone the undersigned in order to resolve such issue(s).

Respectfully submitted,

Dated: 28 February 2008

By: /Daniel M. Chambers/

Daniel M. Chambers
Attorney for Applicant
BioTechnology Law Group
Reg. No. 34,561